UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

GLAXO WELLCOME, INC.,	)	
	)	
Plaintiff,	)	No. C 00-4403 MHP
v.	)	
	)	
IMPAX LABORATORIES, INC.,	)	**MEMORANDUM AND ORDER**
	)	
Defendant.	)	
	)	

On September 28, 2000, Glaxo Wellcome, Inc. filed this patent infringement action against IMPAX Laboratories, Inc. Plaintiff seeks preliminary and final injunctions enjoining further infringement. Now before the court is defendant's motion for summary judgment and plaintiff's motion for *sua sponte* summary judgment. Having considered the parties' arguments and for the reasons set forth below, the court enters the following memorandum and order.

BACKGROUND

Plaintiff Glaxo Wellcome ("Glaxo") is a pharmaceutical company based in Research Triangle Park, North Carolina. Glaxo is the owner of U.S. Patent No. 4,523,798 ("the '798 patent") covering sustained release Wellbutrin® and Zyban®, bupropion hydrochloride tablets marketed to treat depression and aid smoking cessation. Glaxo has marketed an instant release form of these products since 1989. The '798 patent was awarded, however, in recognition of the sustained-release

element (hydroxypropyl methylcellulose, "HPMC") that Glaxo had added to the formulas, allowing users to reduce daily intake to two tablets.

The '798 patent includes nineteen claims. Glaxo alleges that IMPAX's generic product infringes five of these claims (nos. 1, 14, 15, 18 and 19). Each of the disputed claims is independent. Plaintiff explicitly identified HPMC as the sustained-release element from the inception in claim 1. It was not named initially in the remaining claims, but was added during prosecution after the Patent and Trademark Office ("PTO") declared the particular cellulose "critical" to the invention. See Berman Dec., Exh. 5 at PH 75. The amended sustained-release bupropion hydrochloride product is recited in illustrative claims 1, 14 and 18 as follows (independent claims 15 and 19 mirror claims 14 and 18 but are for a 150 mg tablet):[1]

> 1. A controlled sustained release tablet comprising 25 to 500 mg of bupropion hydrochloride and hydroxypropyl methylcellulose [HPMC], the amount of hydroxypropyl methylcellulose to one part of bupropion hydrochloride being 0.19 to 1.1 and said tablet having a surface to volume ratio of 3:1 to 25:1 cm^{-1} and said tablet having a shelf life of at least one year at 59 degrees to 77 F. and 35 to 60% relative humidity[.], said tablet releasing between about 20 and 60 percent of bupropion hydrochloride in water in 1 hour, between about 50 and 90 percent in 4 hours and not less than about 75 percent in 8 hours.
>
> 14. A controlled sustained release tablet comprising an admixture of 100 mg of bupropion hydrochloride and hydroxypropyl methylcellulose [and means for providing a shelf life of at least one year and] which after oral administration of a single one of said tablets in adult men produces plasma levels of bupropion as free base ranging [substantially] between the minimum and maximum levels as shown in Fig. 5 over twenty four hours.
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> 18. A sustained release tablet containing a mixture of (a) 100 mg of bupropion hydrochloride and (b) means for releasing between about 25 and 45% of bupropion hydrochloride in one hour, between 60 and 85% in 4 hours and not less than 80% in eight hours in distilled water said means comprising hydroxypropyl methylcellulose.

Defendant IMPAX, a manufacturer of generic pharmaceuticals based in Hayward, California, has submitted an Abbreviated New Drug Application ("ANDA") to authorize release of generic versions of Wellbutrin® and Zyban®. The generic product does not contain HPMC. Rather, the IMPAX product uses hydroxypropyl cellulose ("HPC") as the extended drug-release agent. Like HPMC, HPC is a popular stabilizing and suspending agent in pharmaceuticals. See Berman Dec., Exhs. 2 & 4 (excerpts from the Handbook of Pharmaceutical Excipients). The substitution of HPC for HPMC appears to be the sole distinction between the two products. All active ingredients and other properties are identical. See Lowman Dec. ¶¶ 11-16.

Plaintiff filed suit on September 28, 2000, alleging that defendant's generic product is substantially equivalent to the '798 patent, and is consequently unallowable under United States patent laws, 35 U.S.C. § 271 et seq. and 21 U.S.C. § 355. Defendant moves for summary judgment dismissing plaintiff's action as a matter of law. Plaintiff also moves this court for *sua sponte* summary judgment. These motions are now before the court.

LEGAL STANDARD

Summary judgment shall be granted when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c). The moving party bears the initial burden of identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. The burden then shifts to the nonmoving party to "go beyond the pleadings, and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (citations omitted). A dispute about a material fact is

genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The moving party discharges its burden by showing that the nonmoving party has not disclosed the existence of any "significant probative evidence tending to support the complaint." First Nat'l Bank v. Cities Serv. Co., 391 U.S. 253, 290 (1968). The court does not make credibility determinations in considering a motion for summary judgment. See Anderson, 477 U.S. at 249. Rather, it views the inferences drawn from the facts in the light most favorable to the party opposing the motion. See T.W. Elec. Serv., Inc. v. Pacific Elec. Contractor's Ass'n, 809 F.2d 626, 631 (9th Cir. 1987).

The same standard is applied by the Federal Circuit. See, e.g., Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995); Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984). Summary judgment is not uncommon in patent actions. See e.g., Wang Lab. v. Mitsubishi Elec. Am., Inc., 103 F.3d 1571 (Fed. Cir. 1997) (prosecution history estoppel precluded finding of infringement); Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285 (Fed. Cir. 1995) (finding prosecution history estoppel on summary judgment).

DISCUSSION

To determine if defendant's product infringes the '798 patent, the court must compare the accused product with the asserted claims of the patent. See Southwall Techs., Inc., 54 F.3d at 1575. A product literally infringes a patent if "every limitation of the patent claim [can] be found in the accused device." Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 981 (Fed. Cir. 1997). Alternatively, a product may be infringing under the doctrine of equivalents if the accused element

"performs substantially the same function, in substantially the same way to obtain the same result" as the claimed invention. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S. Ct. 854, 856 (1950); Warner-Jenkinson Co., 520 U.S. at 35, 117 S. Ct. at 1052.

Each of the disputed claims in the '798 patent (nos. 1, 14, 15, 18, and 19) expressly teaches HPMC as the sustained-release ingredient. See Berman Dec., Exh. 5 PH 11. Defendant's product uses HPC for this purpose. Plaintiff does not contend that HPMC is literally present in the IMPAX product. Instead, plaintiff alleges infringement under the doctrine of equivalents.

The doctrine of equivalents expands a claim beyond the literal scope of the patented language. This prevents an infringer from designing around a claim by finding "[u]nimportant and insubstantial substitutes" for claim limitations. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., __ U.S. __, 122 S. Ct. 1831, 1837 (2002); see also Texas Instruments Inc. v. U.S. Int'l. Trade Comm'n, 988 F.2d 1165, 1173 (doctrine of equivalents prevents "what is in essence a pirating of the patentee's invention"). Under the doctrine of equivalents, the disputed claims would include HPMC and its equivalents. Accord Warner-Jenkinson, 520 U.S. at 35. By this standard, defendant's product infringes the '798 patent if HPC and HPMC are equivalent.

Prosecution history estoppel bars application of the doctrine of equivalents to claims that were expressly narrowed for reasons related to patentability. Festo Corp., 122 S. Ct. at 1839; Warner-Jenkinson, 520 U.S. at 33, 117 S. Ct. at 1051. For instance, if the Patent Trademark Office ("PTO") required an applicant to amend a claim to distinguish an invention from the prior art, the applicant could not later expand its scope beyond the precise terms of the approved claims. Broader construction would be inappropriate, since patent approval was contingent on the exact language incorporated during prosecution. Allowing infringement by equivalents in such cases would allow

the "patentee . . . to obtain through litigation, coverage of subject matter relinquished during prosecution." Haynes Int'l v. Jessop Steel Co., 8 F.3d 1573, 1577 (Fed. Cir. 1993). Where prosecution history estoppel applies, plaintiff may only allege literal infringement.

The Supreme Court recently clarified that prosecution history estoppel is not limited to amendments made to overcome the prior art. See Festo, 122 S. Ct. at 1839-40. Estoppel may be triggered by any narrowing amendments, including those made in response to a section 112 enablement rejection. See id.; see also Southwall Techs.,, 54 F.3d at 1581 ("[W]e previously rejected the . . . argument that . . . prosecution history estoppel is limited only to embodiments shown in the prior art."); Warner-Jenkinson, 520 U.S. at 30-31, 117 S. Ct. at 1049 (finding estoppel for "amendments made to avoid the prior art or otherwise to address a specific concern -- such as obviousness -- that arguably would have rendered the claimed subject matter unpatentable.").

The Festo court rejected a bright-line rule, however, favoring a flexible approach. Festo, 122 S. Ct. at 1841. By this standard, a patentee may rely on infringement by equivalents if she can demonstrate "that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." Id. at 1842. Thus, notwithstanding a narrowing amendment, the doctrine of equivalents may apply if one skilled in the art would not have known to claim both the particular element and its equivalents. Here, plaintiff may not claim infringement by equivalents if (1) HPMC was added to the patent for any reason related to patentability and (2) Glaxo could not have known to construct a claim that literally encompassed both HPMC and HPC. Determining whether estoppel applies is a legal question for the court. Instituform Techs. v. Cat Contracting, 99 F.3d 1098, 1107 (Fed. Cir. 1996).[2]

Plaintiff alleges that defendant has infringed five claims of the '798 patent. Four of these claims were amended during prosecution to include HPMC. Of these, two simply added HPMC as the "critical" time-release excipient (claims 18 and 19). The remaining two claims added HPMC, but simultaneously deleted language pertaining to shelf life (claims 14 and 15). A fifth claim was not amended during prosecution, but included HPMC from the inception (claim 1). Berman Dec., Exh. 5 at PH50-51. The court addresses each subset of claims in turn.

I. Claims Eighteen and Nineteen

The PTO originally rejected claims 18 and 19 under 35 U.S.C. section 112 as being non-enabled. See Berman Dec., Exh. 5 at PH 75. The Examiner maintained that "rate of release is directly related to the release retarding affect [sic] of hydroxypropylmethylcellulose [HPMC]. While other excipients have been disclosed, the particular cellulose is considered critical for controlled and/or sustained release and should be incorporated into the independent claims." Id. Glaxo subsequently amended its patent application, explicitly incorporating HPMC into these claims as required by the PTO. Prosecution history estoppel applies to these claims if (1) the amendments narrowed the patent for reasons related to patentability and (2) a person skilled in the art could have foreseen a less-restrictive alternative.

Plaintiff added HPMC to claims 18 and 19 during prosecution to avoid a section 112 enablement rejection. See Berman Dec., Exh. 5 at PH 75; RT 14 (Wahl) (noting that the PTO twice demanded amendment of these claims). As originally drafted, these claims arguably included every sustained-release formulation. See RT 20 (Berman) ("I submit to the court that every . . . sustained release tablet on the market today, fits within this broad specification"). By replacing the general means-function language with a more-specific claim limitation, plaintiff surrendered all equivalents.

The amendments indisputably narrowed the patent with respect to sustained release. Plaintiff must accept the consequences of these amendments.

Because claims 18 and 19 were narrowed for reasons related to patentability during prosecution, plaintiff may only allege infringement by equivalents if it can prove that inclusion of HPMC did not surrender alternative excipients, such as HPC. Festo, 122 S. Ct. at 1841-42. To do so, plaintiff must demonstrate that one skilled in the art would not have known to expressly include HPC in the amendments. Id. (no estoppel where equivalent unforeseeable during prosecution). Plaintiff cannot meet this burden.

At the time of the disputed amendments, anyone skilled in the art would have known that HPC and HPMC were substantially equivalent. Neither party appears to challenge this equivalency. See, e.g., Pl.'s Opp'n at 12:9-10 ("HPC and HPMC are both sustained drug release implementing polymer hydrogels"); Pl.'s Opp'n at 7-8 (expert testimony highlighting similarities); RT 22 (Wahl) (conceding that plaintiff could claim that HPC is an equivalent). Notably, the Handbook of Pharmaceutical Excipients identifies both HPC and HPMC as related substances. See Berman Dec., Exhs. 2 & 4. The same publication attributes virtually identical uses to both products. Compare id., Exh. 2 ("In oral products, hydroxypropyl methylcellulose [HPMC] is primarily used as a tablet binder, in film-coating and as an extended release tablet matrix.") with id., Exh. 4 ("In oral products, hydroxypropyl cellulose [HPC] is primarily used in tableting as a binder, film-coating and extended release matrix former"). The two chemicals perform substantially the same function (retarding drug release) in the same way (forming a hydrogel) to achieve the same result (sustained release). See Lowman Dec. ¶¶ 14-15.

One skilled in the art would have been aware of these similarities in October 1994, when plaintiff amended its patent. HPC was commonly identified in other products at the time. In fact, myriad products predating the '798 patent identified both HPC and HPMC as the sustained-release ingredient. See, e.g., Def.'s Supp. Opp'n, Exh. 7 (U.S. Patent No. 4,126,672 at C10:L39-60 (issued Nov. 21, 1978)) (providing for a "sustained release pharmaceutical capsule . . . comprising . . . one or a mixture of hydrocolloids selected from the group consisting of . . . hydroxypropylcellulose [HPC], hydroxypropylmethylcellulose [HPMC] . . . [and others]"); Def.'s Supp. Opp'n, Exh. 12 (U.S. Patent No. 5,085,865 at C7:L4-C8:21 (issued Feb. 4, 1992)) (providing for a "sustained-release agent comprising one or more hydrogels selected from the group consisting of water soluble hydorxyalkycelluloses . . . . [including] . . . . hydroxypropyl cellulose [HPC], hydroxypropyl methylcellulose [HPMC], and mixtures thereof"); see also Def.'s Supp. Opp'n, App. C (listing patents providing for both HPC and HPMC). Significantly, plaintiff previously obtained a patent for a sustained-release formulation comprised of both HPC and HPMC. Def.'s Supp. Opp'n, Exh. 11 (U.S. Patent No. 4,897,270 at C8/L30-31 (issued Jan. 30, 1990)). At oral argument, plaintiff conceded that the two chemicals have "been known substitutes for a lot of years." RT 12 (Judlowe). Defendant provided that HPC and HPMC "have been known for decades as polymers that are useful for sustained release." RT 6 (Berman). Since HPC and HPMC were known substitutes by 1994, plaintiff should have known to include HPC in the amendments to claims 18 and 19.

Plaintiff contends that it was unable to identify HPC in the '798 patent because it had not yet been tested as an alternative excipient in this particular product. While this may be true, plaintiff was certainly aware of the possibility that HPC would have a comparable dissolution profile. Given

this likelihood, plaintiff's failure to conduct the necessary analysis or otherwise expand its claims was unreasonable.

Prosecution history estoppel thus bars infringement by equivalents for claims 18 and 19.

II. Claims Fourteen and Fifteen

Plaintiff made two amendments to claims 14 and 15 during prosecution of the '798 patent. First, plaintiff added HPMC to avoid a section 112 enablement rejection. Second, plaintiff deleted language requiring shelf life of "at least one year."

The effect of these amendments is somewhat ambiguous. On the one hand, the explicit inclusion of HPMC narrows claims 14 and 15: these claims are now restricted to drugs containing HPMC. On the other hand, replacement of the shelf-life language with the HPMC element broadens these claims: claims 14 and 15 no longer need to extend shelf life. Plaintiff thus suggests that these claims were broadened during prosecution, barring estoppel. RT 11 (38-39). The court disagrees.

The shelf-life language in the initial patent application was inconsequential. Claims 14 and 15 did not elaborate the mechanism nor rationale for this requirement. The deletion of this language is equally insignificant. Even absent an explicit shelf-life requirement, plaintiff's product has likely retained this property. As plaintiff's counsel acknowledged at oral argument, all commercial products must "last a commercially long period of time." RT 48 (Judlowe).

Notably, the '798 patent is titled "Controlled Sustained Release Tablets Containing Bupropion." Berman Dec., Exh. 5 at PH1. Sustained release is the clear focus of the invention. The amendments to claims 14 and 15 narrowed this teaching.[3]

Prosecution history estoppel thus bars infringement by equivalents for claims 14 and 15.

III. Claim One

Claim 1 is distinct from the other challenged claims because it mentioned HPMC from the inception. For this reason, plaintiff summarily contends: "NO AMENDMENT, NO ESTOPPEL." Pl.'s Opp'n at 17:15 (emphasis in original). Barring estoppel because a patentee never amended a particular claim, however, "exalts form over substance." Haynes Int'l v. Jessop Steel Co., 8 F.3d 1573, 1579 (Fed. Cir. 1993). Contrary to plaintiff's assertion, estoppel may apply to unamended terms. See Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1564 (Fed. Cir. 1990) ("[A] patentee cannot 'recapture through equivalence certain coverage given up [by argument or amendment] during prosecution.'") (quoting Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985)) (brackets in original); Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 5 F. Supp. 2d 399, 404-405 (N.D. Wash. 1998) aff'd 170 F.3d 1373 (Fed. Cir. 1999) (discussing scope of prosecution history estoppel under Federal Circuit precedent and concluding that "an estoppel can be created even when the claim, which is the basis for assertion of infringement under the doctrine of equivalents, was not amended during prosecution.").

Plaintiff is estopped from claiming infringement by equivalents of claim 1 because of amendments to claims 14, 15, 18 and 19. Although HPMC was not added to claim 1 during prosecution, it was added to these other claims. Prosecution history estoppel extends to unamended claims where the challenged element was amended elsewhere in the patent.

Builders Concrete, Inc. v. Bremerton Concrete Products Co., 757 F.2d 255 (Fed. Cir. 1985), is instructive.[4] Builders Concrete had added a "passage" limitation to independent claim 1 during the review process. Id. at 259. Claim 10, which included the passage limitation from the inception, was "allowable as is." Id. After the patent issued, Builders Concrete brought an infringement action

against a competing marine float, arguing that the competing product infringed claim 10 under the doctrine of equivalents. The Federal Circuit rejected this argument, applying prosecution history estoppel to the passage limitation in claim 10 because of amendments made to claim 1 during prosecution. Id. at 260 ("The fact that the 'passage' clause of patent claim 10 was not itself amended during prosecution does not mean that it can be extended by the doctrine of equivalents to cover the precise subject matter that was relinquished in order to obtain allowance of claim 1."). The court encouraged consideration of the prosecution history of all claims when assessing the "fair scope" of the claim in suit. Id.

As in Builders Concrete, HPMC was identified in at least one claim from the start. The limitation was added to other claims during prosecution. In both cases, the amendment was made at the Examiner's request.[4] This bars infringement of claim 1 by equivalents.

Long-standing rules of claim construction also estop plaintiff from invoking the doctrine of equivalents. HPMC is used repeatedly throughout the patent and should be interpreted consistently across claims. The Federal Circuit has long recognized the need to interpret words or phrases consistently both within and across a patent's claims. See, e.g., Phonometrics, Inc. v. Northern Telecom Inc., 133 F.3d 1459, 1465 (Fed. Cir. 1998) ("A word or phrase used consistently throughout a claim should be interpreted consistently"); CVI/ Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1159 (Fed. Cir. 1997) ("[W]e are obliged to construe the term 'elasticity' consistently throughout the claims"); Southwall Techs. v. Cardinal IG CO., 54 F.3d 1570, 1584 (Fed. Cir. 1995) ("[O]nce an argument is made regarding a claim term so as to create an estoppel, the estoppel will apply to that term in other claims").

The meaning of HPMC in claim 1 cannot be determined in isolation. To the contrary, construction of the term in disputed claim 1 requires reference to both the specification and the other claims. The court's narrow construction of HPMC in claims 14, 15, 18 and 19 extends to claim 1. Prosecution history estoppel bars infringement by equivalents throughout the '798 patent. See Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1175 (Fed. Cir. 1993) ("The prosecution history estoppel we hold proven on claim 12 is equally applicable to claims 14 and 17").

For the reasons above, plaintiff may not assert infringement by equivalents of claim 1.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS defendant's motion for summary judgment and DENIES plaintiff's motion for *sua sponte* summary judgment.

IT IS SO ORDERED.

Dated:

MARILYN HALL PATEL
Chief Judge
United States District Court
Northern District of California

ENDNOTES

1. Words added during the prosecution history are underlined; words removed are bracketed.

2. The court is aware that several recent opinions address the applicability of prosecution history estoppel to the '798 patent. In Glaxo Wellcome v. Eon Labs Mfg., Inc., 00-Civ.-9089 (S.D.N.Y. Aug. 13, 2002), the Southern District of New York concluded that prosecution history estoppel does not apply, finding a triable issue of fact as to the foreseeability of HPC as a sustained-release agent. This court does not find the same ambiguity in the record before it. The court respectfully disagrees with that decision. The Eastern District of Virginia considered similar issues in SmithKline Beecham Corp. v. Excel Pharm., Inc., No. 2:02CV51 (E.D. Va. Aug. 2, 2002). Although SmithKline examines the alleged infringement of the '798 patent by a different hydrogel-forming polymer (polyvinyl alcohol), this court agrees with its analysis. As discussed below, this court likewise finds that prosecution history estoppel bars infringement by equivalents of the '798 patent.

3. Plaintiff's reliance on Lockheed Martin Corp. v. Space Systems/ Loral, Inc., 249 F.3d 1314 (Fed. Cir. 2001), is misplaced. Sustained release was not a "completely separate limitation" added to claims 14 and 15 during prosecution. Cf id. at 1327. Rather, HPMC was added to overcome the PTO's section 112 enablement rejection of the sustained-release schedule in the original patent application. See Berman Dec., Exh. 5 at PH 75 (rejecting all independent claims as non-enabled for failure to disclose the particular cellulose providing sustained release). The amendment thus narrowed an existing limitation.

4. Although Builders Concrete was decided in 1985, its broad construction of prosecution history estoppel remains good law and has been repeatedly adopted. See e.g., Intermatic, Inc. v. Lamson & Sessions Co., 273 F.3d 1355, 1366-67 (Fed. Cir. 2001) (extending Builders Concrete to reexamination and holding that "any estoppel generated by [amendment to one claim] applies to all other claims in the patent containing that limitation"); Pall Corp. v. Hemasure Inc., 181 F.3d 1305, 1312 (Fed. Cir. 1999); Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 2001 WL 1035713, *6 (N.D. Ill. 2001) ("Here, [plaintiff] has conceded that Claim 1 of the patent was amended during prosecution . . . . Prosecution history estoppel thus bars the application of the doctrine of equivalents to that element in any claim of the patent, including Claim 4 and dependent Claim 5") (emphasis added).

4. The passage limitation in Builders Concrete was added to avoid prior art, 757 F.2d at 260, while HPMC was added to the '798 patent to address a section 112 enablement rejection. See Berman Dec., Exh. 5 at PH 75. This distinction is insignificant. Both amendments were made for reasons "related to patentability." Festo, 122 S. Ct. at 1840 (**"**A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112 ").